

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK

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JEFFREY KRULEWICH and NORA  
KRULEWICH,

19-cv-2857 (JGK)

Plaintiffs,

MEMORANDUM OPINION AND  
ORDER

- against -

COVIDIEN, LP,

Defendant.

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JOHN G. KOELTL, District Judge:

The plaintiffs, Jeffrey Krulewich and Nora Krulewich, bring this action against Covidien LP asserting 12 claims for common law strict products liability (manufacturing defect, design defect, and failure to warn), negligence, breach of warranty (express and implied), negligent and fraudulent misrepresentation, unconscionable commercial practices under New York General Business Law Sections 349 and 350, unjust enrichment, punitive damages, and loss of consortium. The plaintiffs' claims arise from injuries allegedly sustained because of the implantation of the defendant's synthetic mesh product in Mr. Krulewich's body as part of a hernia repair procedure.

The defendant moves to dismiss the plaintiffs' Second Amended Complaint pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure. For the reasons that follow, and for substantially the same reasons that judges in this district have

dismissed similar recent cases and this Court dismissed the plaintiffs' First Amended Complaint, the defendant's motion to dismiss the Second Amended Complaint is **granted** with prejudice.

**I.**

The following facts are drawn from allegations set out in the Second Amended Complaint and are accepted as true for purposes of this motion to dismiss.

On December 18, 2012, the plaintiff Jeffrey Krulewich underwent an umbilical hernia repair procedure performed by Drs. Sebastian Eid and Aditya Sood. Second Am. Compl. (hereinafter "SAC") ¶ 69. The procedure involved introducing the defendant's Parietex Optimized Composite Mesh (the "Mesh" or the "Product") into Mr. Krulewich's abdominal cavity to reinforce tissue affected by the hernia. Id. ¶¶ 69-70. A hernia is a medical condition caused by the penetration of fatty tissue, intestine, or organs through a weakened or compromised location in the muscle or connective tissue. Id. ¶ 20. Hernia repairs are common surgeries and often involve the use of surgical mesh to strengthen the repair. Id. ¶¶ 24-25. Surgical mesh made from synthetic materials, such as the Mesh, which is made from polyester and an absorbable collagen film, is intended to remain inside the body permanently. Id. ¶¶ 28-29. The Mesh in question was manufactured and sold by the defendant, and a circular, dual-sided 12cm Mesh was used on Mr. Krulewich. Id. ¶ 70.

As a result of alleged Mesh defects, Mr. Krulewich allegedly has experienced abdominal pain since 2018 and has had trouble positioning himself to sleep. Id. ¶ 74. Mr. Krulewich's physician advised him that the Mesh had moved to a different location from where it had been placed, and Mr. Krulewich would have to undergo surgery to remove the Mesh. Id. ¶ 75. Mr. Krulewich also alleges increased risk of organ malfunction, recurrent hernias, perforation of tissue and organs, adherence to tissue and organs, infection, nerve damage, subsequent surgeries, and other complications. Id. ¶ 77. Thus, the plaintiffs alleged economic damages, severe and permanent injuries, emotional distress, mental anguish, and psychological trauma of living with defective products still implanted in Mr. Krulewich's body. Id. ¶¶ 77-78.

The allegation underlying the plaintiffs' strict products liability claims was that "[t]here was an unreasonable risk that the Product would not perform safely and effectively for the purpose for which it was intended, hernia repair," and that the injuries Mr. Krulewich suffered were proximately caused by the product. Id. ¶¶ 84, 89. With respect to the claim for defective design, the plaintiffs alleged that "[a]lternative designs for the Product and/or procedures existed that were and/or are less dangerous and equally, if not more, effective, as well as economically feasible, including the use of polycarbonate,

polystyrene, and polypropene [sic] as alternatives." Id. ¶ 100. The plaintiffs' allegations for failure to warn refer to a number of the defendant's instructions for use, brochures, advertisements, and public warnings, that the plaintiffs alleged "were ambiguous or were not sufficient, accurate or clear." Id. ¶ 121.

The plaintiffs' non-products liability claims arose from the same set of allegations that form the basis for their strict products liability claims. Thus, the plaintiffs' negligence, breach of warranty, negligent and fraudulent misrepresentation, New York statutory consumer fraud, unjust enrichment, punitive damages, and loss of consortium claims arose from the underlying allegations of defective manufacture, defective design, and inadequate warning. Id. ¶¶ 125-228.

On January 25, 2019, the plaintiffs initiated this case in the New York State Supreme Court, New York County, naming the defendant. On March 29, 2019, the defendant removed the case to this Court, based on an amended complaint in the New York State Supreme Court (the "First Amended Complaint"). The defendant properly invoked diversity of citizenship jurisdiction under 28 U.S.C. § 1332. On November 1, 2019, the Court granted the defendant's motion to dismiss without prejudice. The plaintiffs filed the operative Complaint (the "Second Amended Complaint") on

December 3, 2019. The defendant then filed this motion to dismiss the Second Amended Complaint.

This action is substantially similar in its factual allegations and claims to several actions recently brought in this district and dismissed pursuant to Rule 12(b)(6). See Kelly v. Covidien, Inc., No. 19-CV-05497 (S.D.N.Y. Jan. 7, 2020), Dkt. No. 16 (dismissing complaint); Green v. Covidien LP, No. 18-CV-2939, 2019 WL 4142480 (S.D.N.Y. Aug. 30, 2019); Kenneth Dunham v. Covidien, LP, No. 19-CV-2851, 2019 WL 2461806 (S.D.N.Y. May 22, 2019) (hereinafter "Dunham, K."); Kennedy v. Covidien, LP, No. 18-CV-1907, 2019 WL 1429979 (S.D.N.Y. Mar. 29, 2019); Rincon v. Covidien, No. 16-CV-10033, 2017 WL 2242969 (S.D.N.Y. May 22, 2017). This case is also substantially similar to Crystal Dunham v. Covidien, LP, No. 19-CV-2855 (hereinafter "Dunham, C."), before this Court, which this Court also is dismissing in an Opinion being filed contemporaneously with this Opinion.

## II.

In deciding a motion to dismiss pursuant to Rule 12(b)(6), the allegations in the complaint are accepted as true, and all reasonable inferences must be drawn in the plaintiff's favor. McCarthy v. Dun & Bradstreet Corp., 482 F.3d 184, 191 (2d Cir.

2007).<sup>1</sup> The Court's function on a motion to dismiss is "not to weigh the evidence that might be presented at a trial but merely to determine whether the complaint itself is legally sufficient." Goldman v. Belden, 754 F.2d 1059, 1067 (2d Cir. 1985). The Court should not dismiss the complaint if the plaintiff has stated "enough facts to state a claim to relief that is plausible on its face." Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009).

While the Court should construe the factual allegations in the light most favorable to the plaintiff, "the tenet that a court must accept as true all of the allegations contained in the complaint is inapplicable to legal conclusions." Id. When presented with a motion to dismiss pursuant to Rule 12(b)(6), the Court may consider documents that are referenced in the complaint, documents that the plaintiff relied on in bringing suit and that are either in the plaintiff's possession or that the plaintiff knew of when bringing suit, or matters of which

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<sup>1</sup> Unless otherwise noted, this Memorandum Opinion and Order omits all alterations, citations, footnotes, and internal quotation marks in quoted text.

judicial notice may be taken. See Chambers v. Time Warner, Inc., 282 F.3d 147, 153 (2d Cir. 2002).

### III.

The plaintiffs bring the following claims:

(1) manufacturing defect; (2) design defect; (3) failure to warn; (4) negligence; (5) breach of express warranty; (6) breach of implied warranty; (7) negligent misrepresentation; (8) fraudulent misrepresentation; (9) unconscionable commercial practices; (10) unjust enrichment; (11) punitive damages; and (12) loss of consortium.

#### A. Manufacturing Defect

The plaintiffs allege claims for each of the three types of strict products liability that can be asserted in New York: manufacturing defect, design defect, and failure to provide adequate warnings. See Voss v. Black & Decker Mfg. Co., 450 N.E.2d 204, 207 (N.Y. 1983). In Count I, the plaintiffs allege that there was a manufacturing defect that rendered the Mesh unsafe and ineffective. To state a claim for strict products liability under a manufacturing defect theory, a plaintiff must plead "that a specific product unit was defective as a result of some mishap in the manufacturing process itself, improper workmanship, or because defective materials were used in construction, and that the defect was the cause of plaintiff's injury." Colon ex rel. Molina v. BIC USA, Inc., 199 F. Supp. 2d

53, 85 (S.D.N.Y. 2001). Therefore, a manufacturing defect claim will be dismissed if a plaintiff has not alleged that the specific product that allegedly caused the plaintiff's injuries was defective as compared to other products manufactured by the defendant. Goldin v. Smith & Nephew, Inc., No. 12-CV-9217, 2013 WL 1759575, at \*2 (S.D.N.Y. Apr. 24, 2013). A plaintiff may rely on circumstantial evidence to support a manufacturing defect claim if the plaintiff can prove that the product did not perform as intended and excludes all other causes for the product's failure not attributable to the defendant. See id. at \*3 (citing Speller ex rel. Miller v. Sears, Roebuck & Co., 790 N.E.2d 252, 254-55 (N.Y. 2003)).

This Court dismissed the plaintiffs' manufacturing defect claim in the First Amended Complaint because the plaintiffs did not allege plausibly that the specific Mesh implanted in Mr. Krulewich's body was defective due to a specific problem in the manufacturing process that rendered that piece of Mesh different from all other Mesh manufactured by the defendant.

The plaintiffs did not cure the defective pleading. Despite the Court's earlier dismissal of this claim and clear instruction as to how the claim was deficient, the plaintiffs did not substantively amend their manufacturing defect claim. Compare First Am. Compl. (hereinafter "FAC") ¶¶ 77-88 with SAC ¶¶ 79-90. As noted previously, the plaintiffs merely provided

the following conclusory statements: "Defendant's Product was defective in its manufacture"; "the Product deviated from manufacturing standards when it came off the production line"; and "Defendant's Product failed to perform in its intended manner due to a flaw in the manufacturing process, evident by Plaintiff's injuries, which will be established by expert testimony." SAC ¶¶ 81-83. These conclusory statements do not allege plausibly that the Mesh used during Mr. Krulewich's surgery was defectively manufactured. Nor do these statements establish circumstantial evidence of a manufacturing defect because the plaintiffs have not excluded other causes that are not attributable to the defendant. See, e.g., Dunham, K., 2019 WL 2461806, at \*2; Kennedy, 2019 WL 1429979, at \*4 ("Here, Plaintiff does not allege that a particular mishap occurred in the manufacturing process that rendered the specific implanted unit of [the] Mesh defective . . . [n]or does Plaintiff proffer circumstantial evidence showing that the product did not perform as intended and excluding any alternate causes of his injuries."). Therefore, the plaintiffs failed to cure the defect in their manufacturing defect count and fail to state a claim.

#### **B. Design Defect**

In Count II, the plaintiffs allege that the Mesh was defectively designed. The design defect inquiry considers whether "the product is one which, at the time it leaves the

seller's hands, is in a condition not reasonably contemplated by the ultimate consumer and is unreasonably dangerous for its intended use; that is one whose utility does not outweigh the danger inherent in its introduction into the stream of commerce." Voss, 450 N.E.2d at 207 (quoting Robinson v. Reed-Prentice Div. of Package Mach. Co., 403 N.E.2d 440, 443 (N.Y. 1980)). To state a claim for strict products liability under a design defect theory, a plaintiff must allege that "(1) the product as designed posed a substantial likelihood of harm; (2) it was feasible to design the product in a safer manner; and (3) the defective design was a substantial factor in causing plaintiff's injury." Simon v. Smith & Nephew, Inc., 990 F. Supp. 2d 395, 403 (S.D.N.Y. 2013) (quoting Colon, 199 F. Supp. 2d at 83). Courts generally require plaintiffs to allege adequately a safer alternative design. See DiBartolo v. Abbott Labs., 914 F. Supp. 2d 601, 622-23 (S.D.N.Y. 2012) ("[I]t is well settled that to establish a claim predicated upon a design defect, plaintiffs must present evidence that the product, as designed, was not reasonably safe because there was a substantial likelihood of harm and that it was feasible to design the product in a safer manner.") (quoting Sabater ex rel. Santana v. Lead Industries Association, Inc., 704 N.Y.S.2d 800, 804 (Sup. Ct. 2000)).

This Court dismissed the plaintiffs' design defect claim in the First Amended Complaint because the plaintiffs failed to

plead facts showing that there was a safer alternative design. The First Amended Complaint consisted of conclusory statements that merely referred by name to alleged alternatives without providing specific factual pleadings gave rise to a reasonable inference that the alternatives of polycarbonate and polystyrene were, in fact, feasible alternatives. See, e.g., Kennedy, 2019 WL 1429979, at \*4. Without specific factual pleadings adequately alleging an alternative design and causation, the plaintiffs' claim for design defect failed. See, e.g., Green, 2019 WL 4142480, at \*3 ("Simply asserting that a feasible alternative design exists - without pleading any supporting facts - is not sufficient to plead a defective design claim or to put Defendant on notice as to what that design might be.").

In the Second Amended Complaint, the plaintiffs allege that the Mesh was defectively designed in that "[o]nce the Product's polyester fibers unravel, they become detached from the mesh and migrate to other regions of the body," causing inflammation, nerve damage, and nerves that grow into the pores of the Mesh after implant. SAC ¶¶ 53-56. The plaintiffs further allege that "[a]lternative designs for the Product and/or procedures existed that were and/or are less dangerous and equally, if not more, effective, including the use of polycarbonate, polystyrene and polypropene [sic] as alternatives." Id. ¶ 100.

The plaintiffs' proposed alternative design is to use polypropylene instead of polyester. SAC ¶¶ 94, 97. However, other courts considering a similar issue have found that proposal insufficient to support a design defect claim. See, e.g., Dunham, K., 2019 WL 2461806, at \*3 (the design defect claim failed because the plaintiffs "merely allege[d] that . . . different materials like polycarbonate or polystyrene, are safer and more effective alternatives to hernia mesh.").

Moreover, the plaintiffs have not alleged adequately that the failure to use polypropylene caused Mr. Krulewich's injuries, apart from conclusory allegations, such as that the injuries were "a direct and proximate result of the defective and unreasonably dangerous Product." SAC ¶ 108. The plaintiffs allege that "[a] substantial factor causing the Product's defects is Defendant's design and use of polyester material for the Product's mesh rather than the industry standard, polypropylene. Polyester is weaker than polypropylene and therefore more prone to tearing away from the tacks; casuing [sic] severe inflammation. Polyester is also less sturdy than polypropylene, creating difficulty during surgery. Beyond this, unlike most hernia mesh devices, the Product has unsealed edges, causing the Product's edges to fray and disintegrate once the Product has been implanted. Once this has happened, organ perforation can result." SAC ¶ 97. The plaintiffs also cited to

one study that argued that polyester mesh should not be used in hernia repair surgery. Id. ¶ 98.

Despite these allegations that the use of polyester could cause injuries, the plaintiffs have not alleged adequately that the use of polyester in fact was a substantial factor in causing Mr. Krulewich's injuries. See Simon, 990 F. Supp. 2d at 404. To the contrary, the plaintiffs allege that injuries Mr. Krulewich suffered were among the most common injuries caused by hernia surgeries using any type of mesh. SAC ¶¶ 30, 74-77. That one study argued against using polyester mesh is not sufficient to meet the plaintiffs' burden to plead a causal link between the use of polyester and Mr. Krulewich's injuries. And that a polypropylene-based product may be safer, even if true, does not mean that the use of the polyester Mesh caused Mr. Krulewich's injuries. The plaintiffs' threadbare allegation that "Defendant's design and use of polyester material in its hernia mesh Product posed a substantial risk for severe [sic] inflammation and was a substantial factor in causing Plaintiff's [sic] injuries" is likewise insufficient. Id. ¶ 94; see also Iqbal, 556 U.S. at 678 ("Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice" to state a cause of action.). As courts considering similar issues have concluded, the plaintiffs in this case "do[] not address the numerous plausible alternative explanations for

[Mr. Krulewich's] medical problems, including natural complications from his hernia disease or the development of a new hernia." Dunham, K., 2019 WL 2461806, at \*3; see also Rincon, 2017 WL 2242969, at \*1. Therefore, because the plaintiffs have not adequately pleaded that the use of polyester was a substantial factor in causing Mr. Krulewich's injuries, the plaintiffs have failed to allege adequately a design defect claim.

### **C. Failure to Warn**

In Count III, the plaintiffs allege that the defendant provided inadequate warnings about the dangerous risks associated with the Mesh. To state a strict product liability claim for failure to warn, a plaintiff must allege plausibly that "(1) a manufacturer has a duty to warn (2) against dangers resulting from foreseeable uses about which it knew or should have known, and (3) that failure to do so was the proximate cause of the harm." State Farm Fire & Cas. Co. v. Nutone, Inc., 426 Fed. App'x 8, 10 (2d Cir. 2011); Goldin, 2013 WL 1759575, at \*5; see also Liriano v. Hobart Corp., 300 N.E.2d 303, 305 (N.Y. 1998). At the motion to dismiss phase, a plaintiff must plead facts that show how the warning was inadequate or insufficient. See Reed v. Pfizer, Inc., 839 F. Supp. 2d 571, 575 (E.D.N.Y. 2012).

The plaintiffs' failure to warn claim in the First Amended Complaint failed because the plaintiffs did not provide factual support for the conclusory statements that the defendant's warnings "were not sufficient, accurate or clear." FAC ¶ 132; see also Kennedy, 2019 WL 1429979, at \*5 ("Plaintiff has failed to provide factual support for his conclusory assertion that Defendant's warnings did not adequately caution physicians and patients concerning the risks associated with PCOx Mesh."). The plaintiffs' allegations in this regard were entirely conclusory, and did not amount to anything more than repeated statements that the defendant's warnings and instructions for use were inadequate.

The additional allegations in the Second Amended Complaint do not cure the defects in the plaintiffs' failure to warn claim. The plaintiffs added allegations that the defendant failed to warn that: "the Product did not, in fact, provide long term reinforcement of soft tissue while minimizing tissue attachment"; "that Pthe [sic] Product's mesh contracts over time, causing tension to increase where the tacks or sutures secure it and causing eventual tear of the Product's mesh, which is exactly what happened to Plaintiff's Product's mesh"; that the defendant "misrepresented to the medical community that the Product was safe and effective" and "improperly minimized the adverse effects associated with the Product's use" despite

"numerous reports documenting serious adverse events associated with the Product"; that "Defendant's brochure for the Product, . . . provides very minimal amount of information for the general public or the medical community regarding adverse effects, serious risks of physical injury, or warnings of same, that it knew was associated with the Product and its use"; and that "Plaintiff's physicians would not have elected to use Defendant's Product had it been equipped with sufficient warnings, including the possibility for the Product's mesh migration, failure, and need for future surgeries." SAC ¶¶ 113-16, 123.

These additions do not cure the deficiencies in the plaintiffs' failure to warn claim because the allegations do not identify how the warnings given were insufficient to warn physicians and the plaintiffs of the potential dangers of using the Mesh. The warnings given noted the risks of the complications that Mr. Krulewich actually experienced, namely, chronic pain, adhesion, and hernia recurrence. Id. Ex. A.; see also Green, 2019 WL 4142480, at \*5 ("As an initial matter, the injuries that Plaintiff allegedly suffered - recurring hernias, pain, and adhesions - are included in Defendant's warnings as they are set forth in the Amended Complaint.") (emphasis in original); Kennedy, 2019 WL 1429979, at \*5. And beyond conclusory statements, the plaintiffs do not allege adequately

that Mr. Krulewich or his physicians would have chosen not to use the Mesh but for the allegedly inadequate warnings. See, e.g., Dunham, K., 2019 WL 2461806, at \*3 (dismissing the failure to warn claim because the complaint did not “particularize specific omissions or inadequacies supporting its allegations that [the plaintiff’s] physicians would not have elected to use those products if they had been accompanied by adequate warnings regarding the possibility of mesh migration, failure, chronic pain, and need for future surgeries beyond the generally accepted risks of hernia surgery.”). Therefore, the plaintiffs have not adequately stated a failure to warn claim.

#### **D. Negligence**

In Count IV, the plaintiffs allege that the defendant was negligent in designing, manufacturing, and selling its product. SAC ¶¶ 125-133. In New York, claims for negligent design and design-based strict products liability are analyzed identically. See Kennedy, 2019 WL 1429979, at \*5 (citing Denny v. Ford Motor Co., 662 N.E.2d 730, 735-36 (N.Y. 1995)); see also Colon, 199 F. Supp. 2d at 84 (“Failure to warn claims are identical under strict liability and negligence theories of recovery.”); Estrada v. Berkel Inc., 789 N.Y.S.2d 172, 173 (App. Div. 2005) (quoting Martin v. Hacker, 628 N.E.2d 1308, 1311 n.1 (N.Y. 1993)) (“Where liability is predicated on a failure to warn, New York views negligence and strict liability claims as

equivalent.”). Therefore, the plaintiffs’ negligence claim is analyzed under the same standards as set forth in Voss. See, e.g., Adams v. Genie Indus., Inc., 929 N.E.2d 380, 384 (N.Y. 2010) (“Thus, while plaintiff here has pleaded both strict liability and negligent design causes of action, the standards set forth in Voss apply to both.”).

Because the plaintiffs’ strict products liability claims failed as inadequately pleaded, the plaintiffs’ allegations of negligent design, manufacturing, and selling are likewise deficient. See, e.g., Green, 2019 WL 4142480, at \*5 (dismissing negligence claim because strict liability claims fail); Kennedy, 2019 WL 1429979, at \*5 (same). The Second Amended Complaint did not adequately cure the defects with the strict products liability or negligence claims in the First Amended Complaint. Therefore, the plaintiffs failed to state a negligence claim.

#### **E. Breach of Express Warranty**

In Count V, the plaintiffs allege a breach of express warranty. In order to state a claim for breach of express warranty, a plaintiff must show that there was “an affirmation of fact or promise by the seller, the natural tendency of which was to induce the buyer to purchase and that the warranty was relied upon to the plaintiff’s detriment.” Weiner v. Snapple Beverage Corp., No. 07-CV-8742, 2011 WL 196930, at \*5 (S.D.N.Y. Jan. 21, 2011) (quoting Fendi Adele S.R.L. v. Burlington Coat

Factory Warehouse Corp., 689 F. Supp. 2d 585, 604 (S.D.N.Y. 2010). The "natural tendency" element requires that the seller-defendant's statement be "definite enough" such that the natural tendency of the statement would be to induce purchase. See Becker v. Cephalon, Inc., No. 14-CV-3864, 2015 WL 5472311, at \*7 (S.D.N.Y. Sept. 15, 2015). The reliance element requires "no more than reliance on the express warranty as being a part of the bargain between the parties." CBS Inc. v. Ziff-Davis Pub. Co., 553 N.E.2d 997, 1001 (N.Y. 1990).

In the First Amended Complaint, the plaintiffs pointed to several statements made by the defendant that allegedly comprised the express warranty, namely that the Mesh was "safe and effective for the use of hernia repair," that the product was "the most complete hernia repair solution," and that the product was one of "the most studied, innovative and reliable hernia products available today." FAC ¶¶ 143-44. This Court, as did others considering similar claims, found that none of those statements were definite enough for a claim for breach of express warranty to be made out. See, e.g., Kennedy, 2019 WL 1429979, at \*6 ("In the present case, Plaintiff does not identify a specific warranty made by Defendant that he relied on. His characterization of Defendant's marketing material as generally implying that PCOx Mesh was 'safe and effective' does not identify any specific actionable conduct or statement on

behalf of Defendant."); Dunham, K., 2019 WL 2461806, at \*5 (finding that the complaint did not contain an affirmative statement of fact that formed the basis of a warranty because "the statements are generic, indefinite statements about the products at issue"). Moreover, there were no plausible allegations that Mr. Krulewich or his physicians relied on the alleged warranty beyond the plaintiffs' conclusory statement that they did so. See FAC ¶ 147. This kind of conclusory statement of reliance was insufficient to make out a claim for breach of express warranty.

Despite this Court's prior ruling on the motion to dismiss the First Amended Complaint, and the clear instruction as to how the pleading was deficient, the plaintiffs did not substantively amend the breach of express warranty claim. Apart from minor stylistic changes and certain deletions, the only notable addition was an allegation, similar to an allegation in the Dunham, C. Second Amended Complaint, that apparently was left unfinished. In that allegation, the plaintiffs asserted that "Defendant breached the express warranties it made about the Product because[.]" SAC ¶ 139. That is plainly an insufficient basis to state a claim. Therefore, the breach of express warranty claim, as stated in the Second Amended Complaint, fails for the same reasons it failed in the First Amended Complaint.

### F. Breach of Implied Warranty

In Count VI, the plaintiffs allege that the defendant breached an implied warranty that the Mesh was reasonably fit for its intended use and that it was designed, manufactured, and sold in accordance with good design, engineering, and industry standards. SAC ¶¶ 141-48. A claim for breach of an implied warranty in a products liability action focuses on "the expectations for the performance of the product when used in the customary, usual and reasonably foreseeable manners." Denny, 662 N.E.2d at 736. "The implied warranty of merchantability is a guarantee by the seller that its goods are fit for the intended purpose for which they are used and that they will pass in the trade without objection." Caronia v. Philip Morris USA, Inc., 715 F.3d 417, 433 (2d Cir. 2013) (quoting Saratoga Spa & Bath, Inc. v. Beeche Systems Corp., 656 N.Y.S.2d 787, 789 (App. Div. 1997)). To comply with an implied warranty, a seller's goods must be of "a minimal level of quality," but need not "be perfect" or "fulfill a buyer's every expectation." Id. A breach of implied warranty may be established based on circumstantial evidence, and a plaintiff does not need to prove a specific defect. See Dunham, K., 2019 WL 2461806, at \*5.

This Court dismissed the plaintiffs' breach of implied warranty claim in the First Amended Complaint because the plaintiffs' allegations consisted of nothing more than the

conclusory statement that the "hernia mesh product was defective as set forth above, was not fit for its intended use and was not designed, manufactured, or sold in accordance with good design, engineering and industry standards." FAC ¶ 155. Those conclusory allegations were insufficient to state a claim for breach of implied warranty.

The Second Amended Complaint is likewise insufficient to state a claim for breach of implied warranty. Despite this Court's prior ruling on the motion to dismiss the First Amended Complaint, and the clear instruction as to how the pleading was deficient, the plaintiffs did not substantively amend the breach of implied warranty claim. The plaintiffs do not adequately allege that the Mesh was deficient when used in "customary, usual and reasonably foreseeable manners." Denny, 662 N.E.2d at 736; see also Dunham, K., 2019 WL 2461806, at \*5 (dismissing breach of implied warranty claims because "[a]lthough the complaint alleges that [the plaintiff] has experienced stomach pain and recurring hernias following his procedures, those allegations of common consequences of hernia surgeries do not show that Covidien's products were unsafe for hernia mesh repairs"). In this case, as in Dunham, K., the fact that Mr. Krulewich suffered injuries is not sufficient to show that the Mesh was unsafe for use in hernia surgeries. Therefore, the breach of an implied warranty claim in the Second Amended

Complaint fails for the same reasons it failed in the First Amended Complaint.

### **G. Negligent Misrepresentation**

In Count VII, the plaintiffs allege negligent misrepresentation on the theory that the defendant made false representations about the results of the hernia mesh product testing, and that the defendant was negligent in ascertaining the truth of the representations. SAC ¶¶ 149-59. "A negligent misrepresentation is actionable under New York law where the defendant has been careless in imparting words upon which others were expected to rely and upon which they did or failed to act to their damage, and where the author of the statement has 'some relationship or duty . . . to act with care' vis-a-vis the party at whom the statement is directed." Aetna Cas. & Sur. Co. v. Aniero Concrete Co., 404 F.3d 566, 583 (2d Cir. 2005) (quoting White v. Guarente, 372 N.E.2d 315, 319 (N.Y. 1977) (alteration in original)). Claims for negligent misrepresentation that sound in fraud must meet the heightened pleading standard of Federal Rule of Civil Procedure 9(b). See Kennedy, 2019 WL 1429979, at \*6 & n.14; see also Aetna Cas., 404 F.3d at 583. Negligent misrepresentation is established by showing that "(1) the defendant had a duty, as a result of a special relationship, to give correct information; (2) the defendant made a false representation that he or she should have known was incorrect;

(3) the information supplied in the representation was known by the defendant to be desired by the plaintiff for a serious purpose; (4) the plaintiff intended to rely and act upon it; and (5) the plaintiff reasonably relied on it to his or her detriment." Hydro Investors, Inc. v. Trafalgar Power Inc., 227 F.3d 8, 20 (2d Cir. 2000); Eaves v. Designs for Fin., Inc., 785 F. Supp. 2d 229, 254 (S.D.N.Y. 2011).

This Court dismissed the plaintiffs' negligent misrepresentation claim in the First Amended Complaint because the plaintiffs failed to provide any factual support for their allegation that "the misrepresentations made by Defendant were false," FAC ¶ 158, and thus failed to allege an element of a negligent misrepresentation claim under a Rule 12(b)(6) standard, as well as the particularity requirements demanded by Rule 9(b).

In the Second Amended Complaint, the plaintiffs again failed to identify which statements or representations made by the defendant were false and offered no support for the claim that the defendant's representations were indeed false. In fact, the Second Amended Complaint made few substantive changes to the First Amended Complaint with respect to the negligent representation claim. Instead, the plaintiffs allege a conclusory and generalized statement that "[t]he representations made by Defendant were false; Defendant was careless or

negligent in ascertaining the truth of the representations at the time Defendant made these misrepresentations." SAC ¶ 155. To the extent that the plaintiffs do point to particular representations they claim to be false, they fail to provide any factual basis to conclude that those statements were false, misleading, or contained any material omissions. Moreover, the plaintiffs fail to show that the plaintiffs reasonably relied on the alleged material misrepresentations to the detriment of Mr. Krulewich. That Mr. Krulewich suffered adverse consequences from the procedure does not provide sufficient support for the required element that the plaintiffs reasonably relied on misrepresentations by the defendant. Therefore, even without applying the heightened pleading standards of Rule 9, the plaintiffs have failed to state a negligent misrepresentation claim.

#### **H. Fraudulent Misrepresentation**

In Count VIII, the plaintiffs allege that the defendant fraudulently misrepresented material facts and made material omissions from 2011 to the present to the plaintiffs, Mr. Krulewich's physicians, and the medical community to induce them to use the Mesh through brochures, webpages, press releases, advertising campaigns, and other forms of public communications. SAC ¶¶ 160-84.

To state a claim for fraudulent misrepresentation in compliance with Rule 9(b), a plaintiff must "(1) specify the statements that the plaintiff contends were fraudulent, (2) identify the speaker, (3) state where and when the statements were made, and (4) explain why the statements were fraudulent." Stevelman v. Alias Research, Inc., 174 F.3d 79, 84 (2d Cir. 1999).

This Court dismissed the plaintiffs' claim for fraudulent misrepresentation in the First Amended Complaint because the plaintiffs did not explain why or how the statements were fraudulent. There was no factual basis in the First Amended Complaint to conclude that the defendant made false or misleading statements or omissions in marketing the Mesh.

The plaintiffs did not adequately cure that defect in the Second Amended Complaint. While the Second Amended Complaint challenges the defendant's representations in its brochure, the plaintiffs still have not alleged any factual basis for their claims that the defendant's representations were false. And despite the plaintiffs' allegation that "[n]either [Mr. Krulewich] nor his physicians had the same knowledge regarding the serious risks of physical injury that were hidden and not discoverable through the use of reasonable care or inspection, and that were only known by Defendant through its testing of the Product and the testing results," SAC ¶ 157, the defendant did

specifically warn of pain, adhesion, and recurrence as common injuries and known side effects of hernia surgeries using Mesh. See SAC Ex. A; see also Kennedy, 2019 WL 1429979, at \*7 (“Absent from these allegations is any factual basis for Plaintiff’s conclusion that the representations made by the Defendant were false or misleading. In fact, the advertising material incorporated into the Complaint appears to have disclosed the risks of the conditions that Plaintiff has allegedly suffered.”). The absence of a factual basis to support the plaintiffs’ claims that the defendant’s representations were either false or misleading is fatal to the claim. Therefore, the plaintiffs have failed to state a claim for fraudulent misrepresentation.

#### **I. Unconscionable Commercial Practices**

In Count IX, the plaintiffs allege that the defendant used unconscionable commercial practices, deception, fraud, false pretenses, false promises, and misrepresentation, and knowingly concealed, suppressed and omitted material facts with the intent that consumers rely on such concealment, suppression and omission in violation of Sections 349 and 350 of the New York General Business Law. SAC ¶¶ 185-201. In particular, the plaintiffs allege that the defendant failed to disclose known risks. Id. ¶ 189.

Section 349 prohibits “[d]eceptive acts or practices in the conduct of any business, trade, or commerce or in the furnishing of any business, trade or commerce or in the furnishing of any service in this state.” N.Y. Gen. Bus. Law § 349(a). Section 350 prohibits “[f]alse advertising in the conduct of any business, trade, or commerce or in the furnishing of any services in the state.” Id. § 350. Under either section, a plaintiff must allege that the defendant has engaged in “(1) consumer-oriented conduct that is (2) materially misleading and that (3) plaintiff suffered injury as a result of the allegedly deceptive act or practice.” Kennedy, 2019 WL 1429979, at \*7 (quoting Orlander v. Staples, Inc., 802 F.3d 289, 300 (2d Cir. 2015)). Although a plaintiff’s showing necessary for deceptive acts under the statute is lower than for common law fraud, the plaintiff must nevertheless show that the alleged deceptive acts would mislead a reasonable consumer acting reasonably under the same circumstances. See Stutman v. Chemical Bank, 731 N.E.2d 608, 611-12 (N.Y. 2000). Moreover, to establish consumer-oriented conduct, the plaintiff “must demonstrate that the acts or practices have a broader impact on consumers at large.” Oswego Laborers’ Local 214 Pension Fund v. Marine Midland Bank, N.A., 647 N.E.2d 741, 744 (N.Y. 1995).

This Court dismissed the plaintiffs’ claim under Sections 349 and 350 in the First Amended Complaint because the

plaintiffs' conclusory statements did not amount to the necessary showing that the alleged deceptive acts would mislead a reasonable consumer. Nor did the plaintiffs' allegations lead to a conclusion that the defendant's acts or practices had a broader impact on consumers. In the First Amended Complaint, the plaintiffs merely alleged that the "Defendant engaged in consumer-oriented, commercial conduct by selling and advertising the subject product" and that the "Defendant misrepresented and omitted material information regarding the subject product by failing to disclose known risks," which were the proximate cause of Mr. Krulewich's injuries. FAC ¶¶ 193-94, 199.

The claim under Sections 349 and 350 in the Second Amended Complaint suffers from the same defects. The plaintiffs allege that "reasonable patients/consumers acting reasonably, such as [Mr. Krulewich] herein and his physicians, were caused to suffer ascertainable loss of money and property and actual damages." SAC ¶ 187. Beyond this conclusory allegation, the plaintiffs have not alleged how the defendant's acts would mislead a reasonable consumer or that the defendant's acts or practices had a broader impact on consumers at large. See Oswego Laborers, 647 N.E.2d at 744. In fact, the plaintiffs did not add any substantive allegations to the Second Amended Complaint that could support a claim under Sections 349 and 350. Compare FAC ¶¶ 190-205 with SAC ¶¶ 185-201. Therefore, for the same reasons

the plaintiffs' claim under Sections 349 and 350 failed in the First Amended Complaint, the claim under Sections 349 and 350 likewise fails in the Second Amended Complaint.

### **J. Unjust Enrichment**

In Count X, the plaintiffs allege a claim for unjust enrichment. Under New York law, a claim for unjust enrichment requires a showing "(1) that the defendant benefitted; (2) at the plaintiff's expense; and (3) that equity and good conscience require restitution." Beth Israel Med. Ctr. v. Horizon Blue Cross & Blue Shield of N.J., Inc., 448 F.3d 573, 586 (2d Cir. 2006) (quoting Kaye v. Grossman, 202 F.3d 611, 616 (2d Cir. 2000)). A claim for unjust enrichment "is available only in unusual situations when, though the defendant has not breached a contract nor committed a recognized tort, circumstances create an equitable obligation running from the defendant to the plaintiff." Weisblum v. Prophase Labs, Inc., 88 F. Supp. 3d 283, 296 (S.D.N.Y. 2015) (quoting Corsello v. Verizon New York, Inc., 967 N.E.2d 1177, 1185 (N.Y. 2012)).

This Court dismissed the plaintiffs' claim for unjust enrichment in the First Amended Complaint because the plaintiffs did not plead facts plausibly demonstrating that the defendant's product was defective or that the sale was induced through misrepresentation. Consequently, there was no equitable basis for restitution. See, e.g., Kennedy, 2019 WL 1429979, at \*8. The

plaintiffs did not substantively amend their claim for unjust enrichment. Nor did any other of the plaintiffs' amendments provide a basis for equitable relief. As in the First Amended Complaint, the strict liability and misrepresentation claims fail in the Second Amended Complaint, and there is no other equitable basis for the plaintiffs' claim of unjust enrichment. Therefore, the plaintiffs' unjust enrichment claim in the Second Amended Complaint is deficient for the same reasons it was deficient in the First Amended Complaint.

#### **K. Punitive Damages**

In Count XI, the plaintiffs allege a claim for punitive damages because "Defendant knew and recklessly disregarded the fact that its Product caused debilitating and potentially life altering complications with greater frequency than feasible alternative methods and/or products used to treat hernias." SAC ¶ 214.

A punitive damages claim is derivative. Rocanova v. Equitable Life Assur. Soc. of U.S., 634 N.E.2d 940, 945 (N.Y. 1994) ("A demand or request for punitive damages is parasitic and possesses no viability absent its attachment to a substantive cause of action such as fraud."). Because all of the plaintiffs' substantive claims have been dismissed, their claim for punitive damages must be dismissed as well. See, e.g., Kennedy, 2019 WL 1429979, at \*8; Green, 2019 WL 4142480, at \*10;

Rose Lee Mfg. v. Chemical Bank, 588 N.Y.S.2d 408, 410 (App. Div. 1992) ("[C]ause of action seeking to recover punitive damages should also have been dismissed, because a demand for punitive damages does not amount to separate cause of action for pleading purposes."). Moreover, the plaintiffs did not substantively amend their punitive damages claim to assert a separate or new basis for punitive damages. Therefore, the plaintiffs' punitive damages claim in the Second Amended Complaint is deficient for the same reasons it was deficient in the First Amended Complaint.

#### **L. Loss of Consortium**

In Count XII, the plaintiff Nora Krulewich alleges a claim for loss of consortium because she has "suffered and will continue to suffer the loss of her loved one's support, companionship, services, society, love and affection," and because the "marital relationship was impaired and depreciated, and the marital association between husband and wife has been altered." SAC ¶¶ 224-25.

Under New York law, a "claim for loss of consortium or services is a derivative action." Jordan v. Lipsig, Sullivan, Mollen & Liapakis, P.C., 689 F. Supp. 192, 196 (S.D.N.Y. 1988); see also Liff v. Schildkrout, 404 N.E.2d 1288, 1291 (N.Y. 1980) ("Nor can it be said that a spouse's cause of action for loss of consortium exists in the common law independent of the injured

spouse's right to maintain an action for injuries sustained . . . Such a cause of action, however, is a derivative one."). "A spouse cannot recover for loss of consortium unless the defendant is found to be a tortfeasor in causing damages to the other spouse." Jordan, 689 F. Supp. at 196; see also Dunham, K., 2019 WL 2461806, at \*6. As explained above, the plaintiffs have not stated facts sufficient to suggest plausibly that the defendant is a tortfeasor. Therefore, Ms. Krulewich's claim for loss of consortium in the Second Amended Complaint fails for the same reasons it failed in the First Amended Complaint.

#### IV.

The plaintiffs seek, as alternative relief to denial of the motion to dismiss, leave to amend the Second Amended Complaint.<sup>2</sup> "[I]t is often appropriate for a district court, when granting a motion to dismiss for failure to state a claim, to give the plaintiff leave to file an amended complaint." Van Buskirk v. N.Y. Times Co., 325 F.3d 87, 91 (2d Cir. 2003); see also Fed. R. Civ. P. 15(a)(2) ("The court should freely give leave [to amend] when justice so requires."). Leave to amend is in the discretion

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<sup>2</sup> The plaintiffs do not actually move to amend the complaint or seek formal leave to amend, which would require submission of a Proposed Third Amended Complaint. Rather, they request leave to amend as an alternative form of relief in the event that the Court rules against them on the motion to dismiss. "While a court should freely give leave [to amend] when justice so requires, [i]t is within the court's discretion to deny leave to amend . . . when [as here] leave is requested informally in a brief filed in opposition to a motion to dismiss." Chechele v. Scheetz, 466 F. App'x 39, 41 (2d Cir. 2012) (alterations in original).

of the court, and may be denied when there is "undue delay, bad faith or dilatory motive on the part of the movant, repeated failure to cure deficiencies by amendments previously allowed, undue prejudice to the opposing party by virtue of allowance of the amendment, futility of amendment, etc. . . ." Foman v. Davis, 371 U.S. 178, 182 (1962); Anderson News, L.L.C. v. Am. Media, Inc., 680 F.3d 162, 185 (2d Cir. 2012) ("Leave to amend may properly be denied if the amendment would be futile, as when the proposed new pleading fails to state a claim on which relief can be granted."); see also Metzler Inv. GmbH v. Chipotle Mexican Grill, Inc., 970 F.3d 133, 146 (2d Cir. 2020).

In this case, further amendment of the complaint would be futile. This Court already dismissed the plaintiffs' First Amended Complaint without prejudice. Although the Court explained why the plaintiffs' pleading was defective, the plaintiffs failed to cure the defects. The thrust of the plaintiffs' allegations is that the Mesh was defective and caused Mr. Krulewich's injuries, but despite multiple attempts, the plaintiffs have not been able to allege that the Mesh actually caused Mr. Krulewich's injuries. Instead, the plaintiffs only assert generalized propositions that polyester mesh can cause injuries in patients. The plaintiffs' inability to tie any defect in the Mesh to Mr. Krulewich's injuries highlights the futility of their claims. Other courts

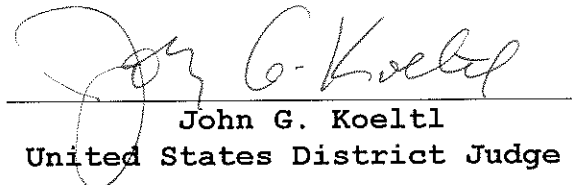
considering similar claims concerning Covidien's Mesh have dismissed the cases for failure to state a claim. In addition to being futile, further leave to amend would cause undue prejudice to the defendant because it would force Covidien to continue litigating a claim for which the plaintiffs have no legal basis. Therefore, the Court declines to grant the plaintiffs leave to amend the Second Amended Complaint.

#### CONCLUSION

The Court has considered all of the arguments of the parties. To the extent not discussed above, the arguments are either moot or without merit. For the foregoing reasons, the defendant's motion to dismiss is **granted**. The plaintiffs' informal request for leave to amend the Second Amended Complaint is **denied**. The Clerk is directed to enter judgment dismissing this case with prejudice. The Clerk is also directed to close Docket No. 25 and to close this case.

SO ORDERED.

Dated: New York, New York  
October 9, 2020

  
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John G. Koeltl  
United States District Judge